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December 21, 2020

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US
Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, NJ 08101

Honorable Joel Schneider, U.S.M.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US
Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, NJ 08101

Re: IN RE: VALSARTAN, LOSARTAN, & IRBESARTAN PRODUCTS
LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Kugler and Judge Schneider:

Please accept this letter on behalf of the Plaintiffs in advance of the December 22, 2020
case management conference.

1. Request for Modifications to Case Management Schedule:

The parties are meeting and conferring about jointly proposing modifications to CMO 22
which would extend certain discovery beyond April 1, 2021, without disruption to existing
deadlines for Daubert briefing and hearings, and include a parallel track for Class Certification
briefing in this CMO. The parties hope to present a joint proposal by tomorrow's conference or

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request a separate conference with the Court dedicated to this subject to take place no later than early next week.

2. Manufacturer Deposition Issues:

Defendants' liaison counsel requested at the most recent status conference that the Court should determine the number of depositions permitted to taken by Plaintiffs of API and finished dose manufacturer witnesses, and the length of the depositions. Based upon ongoing discussions, Defendants have agreed that it is premature to address the length of depositions, thus that is not an issue. The only defendant challenging the number of depositions requested to date is ZHP, so that is the only Defendant as to which there is an issue to be discussed. It is likely that there will not be such a dispute with the other Defendants, and there is no reason to argue a hypothetical dispute that may never need to be addressed.

By way of background, at the writing of this letter Plaintiffs are still awaiting confirmed lists of the 30b6 witnesses who will address each 30b6 topic. The most that has been disclosed, for a few manufacturers, has been the names of those who will address 30b6 topics, and in a few cases the general areas that are expected to be addressed by various witnesses or a handful of topics a witness may address. Thus, Plaintiffs do not have a clear picture of how many and which witnesses will address which topics. Defendants have repeatedly advised that they have until December 23, 2020 to make these disclosures. With the exception of ZHP it is premature to argue about the number of witnesses to be deposed when no other Defendant has objected to the number identified by Plaintiffs to date, and frankly Plaintiffs do not believe there will or should

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be such a dispute to be resolved as Plaintiffs have significantly limited the numbers of witnesses targeted for depositions.

On December 18, 2020, Plaintiffs discussed the witnesses to be produced by ZHP. ZHP had provided a list of some of the witnesses prioritized by Plaintiffs, with dates offered. Plaintiffs accepted the dates for four of the witnesses, subject to later discussion on the length of the depositions. As to the rest, Plaintiffs raised questions. For example, Jun Du, who resides in New Jersey, was offered in March, 2021 (and will not be designated on any 30b6 topics). **Plaintiffs questioned the decision not to designate Mr. Du to testify regarding any 30b6 topics, asked to depose Mr. Du up front at the start in January or early February, 2021, and were told that Mr. Du is unavailable at that time as he is traveling to China in January!** Similarly, every witness who resides in China, inclusive of all of the 30b6 witnesses addressing the core issues such as testing, the development of the manufacturing process, and cGMP and quality assurance activities, has been offered in March, with several during the last days before, and in one case on the date Plaintiffs' expert reports are due. During the December 18, 2020 call defense counsel advised that it is impossible to produce these witnesses, whose testimony is critical to Plaintiffs' expert reports in many cases, until March. Plaintiffs were advised this is due to quarantine issues and the loss of the entire month of February due to the holiday in China. Thus, the first month and a half of the mere 2 and one-half months allotted to take depositions cannot be used to depose the key liability/general causation witnesses from ZHP who are needed for Plaintiffs to understand masses of documents, and advance expert reports. ZHP did agree to try to alter the scheduling within the month of March, which is marginally

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helpful but not a solution to the overall problem of bottlenecking key testimony from ZHP, and likely other Defendants, in the final days before expert reports are due. In light of those discussions, Plaintiffs expect that ZHP will not again state that Plaintiffs should be forced to accept the dates offered by ZHP.

This issue is very difficult and compounds the tremendous time squeeze that is being put on the Plaintiffs to conduct depositions of all manufacturer defendants, and produce expert reports in a matter of a few months. This is notwithstanding that the Defendants have been given multiple lengthy extensions and well over a year to produce their documents, beginning with the core discovery documents. It is thus very important that whatever scheduling is confirmed is equitable, and not severely prejudice Plaintiffs' development of the deposition testimony and expert reports.

3. ZHP Witness Disputes

At the outset it is important to remind the Court of the complex, interrelated corporate organizational structure for ZHP, since the "ZHP" witnesses to be deposed are in numerous cases employed by ZHP subsidiaries and affiliates that defense counsel asserts are truly separate entities, but who are acknowledged to be necessary to respond to various topics. Plaintiffs seek to depose individuals from six ZHP entities:

- (1) ZHP itself,
- (2) Shanghai Syncores (which developed ZHP's manufacturing process for Valsartan API),
- (3) Prinbury (which developed the manufacturing process for Valsartan finished dose),

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- (4) Huahai US (ZHP's U.S. agent to the FDA and at least partially responsible for ZHP's sales, as recognized by ZHP's proffer of Eric Iozzia, Director of Sales at Huahai US, who reports to ZHP's sales department, as a deponent),
- (5) Princeton (another entity that handles parts of ZHP's regulatory affairs in the U.S.), and
- (6) Solco (who sold and distributed ZHP's finished dose Valsartan in the U.S.).

Plaintiffs have requested the depositions of 20 witnesses under the ZHP umbrella, broken down as follows:

- (1) John Iozzia, Director of Sales at Huahai US **(agreed)**,
- (2) Lijie Wang, Vice President of Regulatory Affairs at Princeton **(agreed)**,
- (3) Remonds Gergis, Vice President of Quality Assurance at Princeton **(agreed)**.
- (4) Hai Wang, President of Solco (formerly at Huahai US and Princeton) **(agreed)**,
- (5) Jun Du, CEO of Prinbury, Huahai US, Princeton, and Solco **(agreed)**,
- (6) Jay (Jie) Wang, Vice President of Business Development at ZHP **(agreed)**,
- (7) Linda (Lihong) Lin, Director of Regulatory Affairs at ZHP **(agreed)**,
- (8) Peng Dong, Deputy Director of Technology (Manufacturing), Department I at ZHP **(agreed)**,
- (9) Hong (Eric) Gu, President of Shanghai Syncores **(agreed)**,
- (10) Minli Zhang, Director of Finished Dose Formulation Quality at ZHP **(agreed)**,
- (11) Qiangming Li, Senior Director of Analysis at ZHP **(agreed)**,
- (12) Min Li, Vice President of Analysis and Testing at ZHP **(agreed)**,
- (13) Jucai Ge, Director of API Quality Assurance at ZHP **(agreed)**,

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- (14) Xiaodi Guo, Vice President of Huahai US and Prinston **(agreed)** (ZHP has agreed to Mr. Guo as a deponent; however, he is currently “stuck” in China, and the Parties do not know when he will be able to return to the U.S., where the Parties intend to take his deposition),
- (15) Yuelin Hu, Assistant Director of Quality Operation, Department I, at ZHP **(disputed)**,
- (16) Yanfeng (Lucy) Liu, Deputy Director & Manager of API Regulation, at ZHP **(disputed)**,
- (17) Fengyang (Xavier) Tang, Assistant Manager of Business Development, Group I, at ZHP **(disputed)**,
- (18) Mi (Karen) Xu, Senior Director of Market Development at ZHP **(disputed)**,
- (19) Eric Tsai, General Manager of Prinbury **(disputed)**, and
- (20) Baohua Chen, General Manager of ZHP and CEO of Shanghai Syncores **(disputed)**.

Preliminarily, Plaintiffs anticipate ZHP’s primary argument against the disputed deponents to be alleged duplication with already agreed witnesses. However, ZHP has proffered such facially “duplicative” deponents in ZHP’s Analysis and Testing Department: Min Li and Qiangming Li, because the subject matter is massive, and many more than the 20 witnesses requested to date have had significant involvement in key aspects of this case. Clearly, ZHP understands that Plaintiffs cannot be expected to rely solely on one witness from each of ZHP’s departments. Additionally, as Plaintiffs previously noted in their last submission with the Court, many ZHP employees appeared to utilize Hotmail accounts to communicate with customers and other third-parties. Moreover, Plaintiffs have now seen in documents that ZHP employees utilized private

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commercial chatting applications such as WeChat and Skype to communicate with customers. Plaintiffs believe that for some of these customer-facing employees, individual depositions are necessary to address this information. As such, Plaintiffs ask the Court to order the depositions of the following individuals:¹

Yuelin Hu: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ Plaintiffs have redacted the substance of their discussion of each disputed custodian in the letter filed on ECF because it contains extensive descriptions and quotations from documents that Defendants have over-designated as confidential. Plaintiffs will email an unredacted copy of this letter to the Court and Defendants' Liaison Counsel. The respective Defendants can then decide whether to file a motion to seal this letter and the attached Exhibits.

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[REDACTED]

[REDACTED]

Yanfeng (Lucy) Liu:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Fengyang (Xavier) Tang:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Mi (Karen) Xu: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Eric Tsai: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

Baohua Chen

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

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[REDACTED]

4. Teva TAR Protocol

Plaintiffs and Teva reached agreement on the Protocol to govern Teva's continued search of custodial documents, and the Protocol is being submitted to the Court under separate cover.

5. Plaintiffs' Additional Discovery of Wholesaler and Retail Pharmacy Defendants

On December 8, 2020, Plaintiffs served Wholesaler and Retail Pharmacy Defendants with two forms of draft discovery: (i) second sets of document requests, and (ii) Rule 30(b)(6) deposition notices. (*See* Exs. BB & CC). Plaintiffs' intention was to confer with Defendants about the scope, for the final document requests and notices to be entered by the Court, as have been the practice in this litigation with all other discovery to date. However, Wholesaler and

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Retail Pharmacy Defendants have refused to meet and confer about Plaintiffs' draft discovery. Instead, Wholesaler and Retail Pharmacy Defendants claim that any additional discovery directed to them should occur after the current April 1 discovery deadline, or even after an order on class certification.

This is improper. The current discovery schedule calls for the completion of all fact discovery by April 1, 2021. Plaintiffs cannot agree to serve – let alone even discuss – additional discovery on two tiers of Defendants until *after* the current fact discovery deadline.

Additionally, Plaintiffs' additional document requests and deposition notices are narrowly targeted on important liability and class issues. The document requests largely focus on very discrete, highly relevant documents; for example, warranties received and made about VCDs, inventory management policies, and purchase/sales agreements for VCDs. Notably, Retail Pharmacy and Wholesaler Defendants do not even object or argue to the substance of any requests; they merely claim they should not even have to deal with this discovery until many months from now.

Plaintiffs had agreed to table additional discovery of Wholesaler and Retail Pharmacy Defendants when Plaintiffs negotiated their first sets of document requests to these Defendants (which took from December 2019 to July 2020). The expectation at that time was that the parties' efforts should initially focus on Manufacturer Defendants, with additional discovery of Wholesaler and Retail Pharmacy Defendants to follow. The time for that additional discovery to follow, however, is now.

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Similarly, Plaintiffs' corporate deposition notices are tailored to the issues unique to the Wholesaler and Retail Pharmacy Defendants in this case. There is no basis, in the existing schedule or otherwise, for these Defendants to unilaterally resist deposition discovery until *after* the Court's April 1, 2021 deadline.

For these reasons, given Wholesaler and Retail Pharmacy Defendants refusal to even meet and confer about Plaintiffs' proposed deposition notices and document requests, the Court should find these Defendants have waived any objections to them and enter Plaintiffs' notices and document requests as Exhibits DD & EE.

6. Issues With Wholesaler Defendants' DFSs and Plaintiffs' First Set of Document Requests to Wholesaler Defendants

Plaintiffs are pleased to report that, since the last CMC, the parties have agreed to a schedule for Wholesalers' completion of Defendant Fact Sheets.

There remains, however, ripe disputes concerning Wholesaler Defendants' responses and objections to Plaintiffs' first set of documents (which were entered in July 2020, after months of negotiation, letter briefing, and argument). Plaintiffs first raised these issues with Wholesaler Defendants on November 18, 2020. (*See* Ex. FF hereto). Following a meet and confer on December 1, Wholesaler Defendants did not follow up again until December 17 but only to respond that *any* issue concerning these prior requests should be handled by way of Plaintiffs serving *new* document requests. (*See* Ex GG hereto). This of course is ironic because, as discussed above, Wholesaler Defendants have refused even to meet and confer about Plaintiffs' draft second set of document requests, and further contend any further discovery of them should take place *after* the current April 1 discovery deadline.

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First, all three Wholesaler Defendants have objected to producing data responsive to the court-ordered document requests on the basis that the Drug Supply Chain Security Act (“DSCSA”) prohibits them from doing so, even under court order. (*See* Ex. GG hereto(Wholesaler Defendants’ Objs. & Resps.)). Wholesaler Defendants never raised this issue in the months-long meet and confer process, in letter briefing to the Court, or during lengthy oral argument. Thus, any belated “objection” to producing responsive data has been waived. Further, the Confidentiality Order in this case vitiates any confidentiality concerns. Finally, Wholesaler Defendants’ assertion that Plaintiffs should just get bits of this same data from Manufacturer and Retailer Defendants, and piece it together themselves to infer what Wholesaler Defendants might possess, is no solution. As the party resisting discovery, it is Wholesaler Defendants’ burden to show that the data they possess is duplicative of data from other sources. They cannot hoist upon Plaintiffs the burden of guessing what data each Manufacturer or Retail Pharmacy Defendant might send or receive to each Wholesaler Defendant, and in turn what might reside in each Wholesaler Defendant’s files. In lieu of the data production, Plaintiffs are not opposed to a stipulation to the effect that each Wholesaler Defendant has and maintains all of the data required by the DSCSA for VCDs, and specifying what data fields they receive from each Manufacturer, or send to each Retail Pharmacy Defendant. But to date, Wholesaler Defendants have not been willing to discuss the contours of such a stipulation. Thus, Plaintiffs have no choice but to insist that Wholesaler Defendants produce that which they *agreed* to produce in the court-ordered document requests. The Court’s recent Motion to Dismiss ruling rejecting preemption under the DSCSA only serves to highlight that the DSCSA’s provisions were meant to co-exist with judicial proceedings. Wholesaler Defendants’ arguments that

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they are prohibited by the DSCSA from producing this information should be flatly rejected at this point.

Second, each Wholesaler Defendant has heavily redacted agreements they have for the purchase or sale of VCDs. They also treated the agreed-upon document request calling for “documents sufficient to identify a list of your significant employees involving in managing the recall of VCDs” as an interrogatory. Instead of producing documents, they each provided a narrative answer identifying a single employee. (*See* Exs. GG (at Resps. to Req. No. 16)). After Plaintiffs waited for weeks to hear Wholesaler Defendants’ final position on all of this, Wholesaler Defendants responded that these issue are subsumed by Plaintiffs’ new draft document requests – the same requests Wholesaler Defendants refuse to meet and confer about, and which they say should not be answered until after the April 1 fact discovery deadline. Wholesaler Defendants cannot have it both ways. They either need to produce documents in response to the existing court-ordered document requests, or in response to Plaintiffs’ proposed second set of document requests. They cannot leave the production of these highly relevant documents in limbo by gaming the meet and confer process and court-ordered discovery schedule.

7. Deposition Protocol Addendums:

Plaintiffs have reached agreement with the Defendants regarding the Chinese and Indian national addendums. Teva previously advised that there may not be a need to pursue a third Addendum, and would forward a proposed revised version if it becomes necessary. That Addendum is awaited and the parties can update the Court at the conference.

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8. Torrent Confidentiality Designations:

Plaintiffs are in receipt of Torrent's submission to the Court. First, Plaintiffs reiterate that Torrent did not timely move to maintain the confidentiality designations per the terms of the Confidentiality Order. This is not disputed. Plaintiffs maintain that none of the documents reach the level of sensitivity required to justify the designations, and in particular information regarding the recalls, the manufacturing process changes, internal scrutiny of quality assurance issues, and internal discussion of the need to reimburse customers. All must be seen in the larger context of a worldwide health and safety crisis resulting from this and the other Defendants' carelessness fueled by a motive to cut costs for profit reasons, the details of which have been disclosed to a large extent through FDA communications. The public health ramifications of this crisis outweighs all of the arguments for confidentiality, to the extent any of these documents may be seen to approach the level of sensitivity needed to justify these designations. Plaintiffs request an order de-designating the five exemplars at issue, and directing Torrent to bring its entire document production into compliance with the Court's ruling.

9. Joint Stipulation Regarding Dismissal of Torrent Private Ltd.

Torrent filed a joint stipulation regarding the dismissal of Torrent Private and the acceptance of service of Torrent Pharmaceuticals on November 13, 2020. (ECF 630). Plaintiffs respectfully ask the Court to approve this joint stipulation.

Respectfully,



ADAM M. SLATER